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10/815,369	04/01/2004	Vineet Kumar Sarin	KIN020	8231
23935 7590 03/10/2010 KOPPEL, PATRICK, HEYBL & DAWSON 2815 Townsgate Road SUITE 215 Westlake Village, CA 91361-5827				
EXAMINER				
PANI, JOHN				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/815,369

Applicant(s)

SARIN ET AL.

Examiner

JOHN PANI

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-8) in the reply filed on 12/17/2009 is acknowledged.

Drawings

2. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 1, 3, and 6-8 are objected to because of the following informalities:

In reference to Claim 1

In line 1 it is suggested to replace "the plane" with --a plane-- as the former lacks antecedent basis. In line 5 it is suggested to insert --the method-- prior to "comprising".

In line 5 it is suggested to replace "the steps" with --steps-- as the former lacks antecedent basis.

In reference to Claim 3

In line 3 it is suggested to replace "a plurality" with --the plurality-- in order to clarify that the reference is to the feature introduced in claim 1.

In reference to Claim 6

In line 2 it is suggested to replace "a patient positioning frame" with --the patient positioning frame-- in order to clarify that the reference is to the feature introduced in claim 1.

In reference to Claim 7

In line 2 it is suggested to replace "a patient positioning frame" with --the patient positioning frame-- in order to clarify that the reference is to the feature introduced in claim 1.

In reference to Claim 8

In line 1 it is suggested to replace "the further" with --a further-- as the former lacks antecedent basis.

4. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Line 3 of claim 1 recites "via a tracking system, suitable for use in navigating". It is unclear what is "suitable for use" (i.e. "a tracking system", "A method", etc.). For purposes of examination the limitation has been interpreted to include any previously defined feature being "suitable for use in navigating".

Claims 2-8 are indefinite by virtue of depending from an indefinite base claim.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 6, respectively of copending Application No. 10/637,304. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application clearly anticipate the corresponding claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 6, respectively of copending Application No. 12/152,707. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application clearly anticipate the corresponding claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2004/0102792 to Sarin et al. ("Sarin '792")

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Sarin '792 teaches:

In reference to Claim 1

A method of determining the plane of a surgical patient's pelvis and inputting that plane into a computer via a tracking system, suitable for use in navigating partial or total

hip replacement surgery (see [0012]), comprising the steps of: aligning the patient in relation to a patient positioning frame (see Fig. 10) with pelvic anatomical features of the patient disposed in secure mechanical relationship with corresponding patient-engaging features (146, 162) on said positioning frame (see [0052]); acquiring with a tracking system the positions of a plurality of index points, said index points constrained to lie in a predetermined relationship with an anterior pelvic plane (APP) defined by the patient-engaging features on said positioning frame (see [0056]); and defining a pelvic plane by calculation based upon the acquired positions of said index points and the predetermined relationship between said APP and said index points (see [0056]).

In reference to Claim 2

The method of claim 1 (see above) wherein said patient engaging features comprise: at least one feature (160) adapted to engage an anterior superior iliac spine; and a feature (162) adapted to engage a patient close to the pubic symphysis (see [0052]).

In reference to Claim 3

The method of claim 2 (see above) wherein said step of acquiring with a tracking system the positions of a plurality of index points includes touching at least one of said index points with a trackable probe (see [0056]).

In reference to Claim 4

The method of claim 3 (see above) wherein said index points comprise at least three index points (171-173), three of said points defining a plane.

In reference to Claim 5

The method of claim 3 (see above) wherein said index points define a coordinate system with known rotational relationship to said APP (see [0056]).

12. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2008/0221570 to Sarin et al. ("Sarin '570").

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Sarin '570 teaches:

In reference to Claim 1

A method of determining the plane of a surgical patient's pelvis and inputting that plane into a computer via a tracking system, suitable for use in navigating partial or total hip replacement surgery (see [0012]), comprising the steps of: aligning the patient in relation to a patient positioning frame (see Fig. 10) with pelvic anatomical features of the patient disposed in secure mechanical relationship with corresponding patient-engaging features (146, 162) on said positioning frame (see [0052]); acquiring with a tracking system the positions of a plurality of index points, said index points constrained to lie in a predetermined relationship with an anterior pelvic plane (APP) defined by the patient-engaging features on said positioning frame (see [0056]); and defining a pelvic plane by

calculation based upon the acquired positions of said index points and the predetermined relationship between said APP and said index points (see [0056]).

In reference to Claim 2

The method of claim 1 (see above) wherein said patient engaging features comprise: at least one feature (160) adapted to engage an anterior superior iliac spine; and a feature (162) adapted to engage a patient close to the pubic symphysis (see [0052]).

In reference to Claim 3

The method of claim 2 (see above) wherein said step of acquiring with a tracking system the positions of a plurality of index points includes touching at least one of said index points with a trackable probe (see [0056]).

In reference to Claim 4

The method of claim 3 (see above) wherein said index points comprise at least three index points (171-173), three of said points defining a plane.

In reference to Claim 5

The method of claim 3 (see above) wherein said index points define a coordinate system with known rotational relationship to said APP (see [0056]).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarin '792 as applied to claim 1 above, and further in view of WO 01/21084 to Hodgson et al. ("Hodgson").

In reference to Claim 6

Sarin '792 teaches the method of claim 1 (see above) and further teaches the step of aligning the patient comprises adjusting an adjustable portion of the frame in relation to the patient (see [0052]). However, Sarin does not appear to explicitly disclose that this occurs with said adjustable portion of said positioning frame detached from an operating table.

Hodgson teaches a method for contacting various points on the pelvis in which the contact blocks are adjusted with the patient in the standing position (see pg. 18 line 20 – col. 19 line 25). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Sarin by detaching the frame from the operating table in order to adjust the ASIS and pubic contact blocks as this simple substitution would predictably result in the user placing the contact blocks on the desired anatomical landmarks as taught by Hodgson and required by Sarin.

In reference to Claim 7

Sarin in view of Hodgson teaches the method of claim 6 (see above) and Hodgson further teaches the adjusting of said frame with the patient in either an upright or a supine position (see Fig. 1a and 1b and pg. 18 line 20 - pg. 18 line 25).

In reference to Claim 8

Sarin in view of Hodgson teaches the method of claim 7 (see above). Sarin further teaches relocating the patient onto an operating table; arranging said patient in the lateral decubitus position (see [0049]); and clamping said patient securely between said adjustable portion (140) of said frame on one side, and an opposing backrest (130) on the other to hold said patient's pelvis in fixed position. While the prior art does not explicitly teach that the relocating happens after adjusting the frame, the proposed combination would suggest this timing to one of ordinary skill in the art, as Hodgson teaches adjusting while the patient is standing and Sarin teaches that the patient is placed on an operating table in the lateral decubitus position after adjustment.

15. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarin '570 as applied to claim 1 above, and further in view of Hodgson.

In reference to Claim 6

Sarin '570 teaches the method of claim 1 (see above) and further teaches the step of aligning the patient comprises adjusting an adjustable portion of the frame in relation to the patient (see [0052]). However, Sarin does not appear to explicitly disclose that this occurs with said adjustable portion of said positioning frame detached from an operating table.

Hodgson teaches a method for contacting various points on the pelvis in which the contact blocks are adjusted with the patient in the standing position (see pg. 18 line 20 – col. 19 line 25). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Sarin by detaching the frame

from the operating table in order to adjust the ASIS and pubic contact blocks as this simple substitution would predictably result in the user placing the contact blocks on the desired anatomical landmarks as taught by Hodgson and required by Sarin.

In reference to Claim 7

Sarin in view of Hodgson teaches the method of claim 6 (see above) and Hodgson further teaches the adjusting of said frame with the patient in either an upright or a supine position (see Fig. 1a and 1b and pg. 18 line 20 - pg. 18 line 25).

In reference to Claim 8

Sarin in view of Hodgson teaches the method of claim 7 (see above). Sarin further teaches relocating the patient onto an operating table; arranging said patient in the lateral decubitus position (see [0049]); and clamping said patient securely between said adjustable portion (140) of said frame on one side, and an opposing backrest (130) on the other to hold said patient's pelvis in fixed position. While the prior art does not explicitly teach that the relocating happens after adjusting the frame, the proposed combination would suggest this timing to one of ordinary skill in the art, as Hodgson teaches adjusting while the patient is standing and Sarin teaches that the patient is placed on an operating table in the lateral decubitus position after adjustment.

16. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/062248 to Chen et al. ("Chen") in view of US Pat. No. 6,311,349 to Kazakia et al. ("Kazakia").

In reference to Claim 1

Chen teaches a method of determining the plane of a surgical patient's pelvis and inputting that plane into a computer via a tracking system, suitable for use in navigating partial or total hip replacement surgery, comprising the steps of: acquiring with a tracking system the positions of a plurality of index points (see pg. 12 line 12 - col. 13 line 5; note that the Examiner interprets the claimed "index points" as being read on by the points on the body which are touched by the tracking probe), said index points constrained to lie in a predetermined relationship with an anterior pelvic plane (particularly, in the above interpretation, the "index points" are three points on the anterior pelvic plane); and defining a pelvic plane by calculation based upon the acquired positions of said index points and the predetermined relationship between said APP and said index points (see pg. 14 lines 13-28; note that because the index points – i.e. locations touched by probe-- lie on the APP as detailed above, and these points are used in calculations to determine the frontal pelvic plane it is submitted that this limitation is taught by Chen; in other words, Chen essentially predetermines that the APP equals the plane including the three recorded points).

However, Chen does not explicitly teach a step of aligning the patient in relation to a patient positioning frame with pelvic anatomical features of the patient disposed in secure mechanical relationship with corresponding patient-engaging features on said positioning frame or that the anterior pelvic plane is defined by the patient-engaging features on the positioning frame.

Kazakia teaches a method (see col. 2-col. 5) of stabilizing a patient for hip surgery in which the patient is aligned in relation to a patient positioning frame (at least

100 and 200) with anatomical features of the patient disposed in a secure mechanical relationship with corresponding patient-engaging features (110, 120, 140) on said positioning frame. Kazaki teaches that the method provides improved and repeatable pelvic positioning relative to an operating table (see col. 1).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Chen by including a step of positioning the patient in the device of Kazakia in order to precisely and repeatably orient the patient as taught by Kazakia. Because Kazakia teaches that the pads contact the body at the pubic tubercles and both ASIS, they would further define the APP, and therefore the combination would disclose the claimed method.

In reference to Claim 2

Chen in view of Kazakia teaches the method of claim 1 (see above) and Kazakia further teaches the patient engaging features comprise: at least one feature adapted to engage an ASIS; and a feature adapted to engage a patient close to the pubic symphysis (see col. 3 lines 1-17).

In reference to Claim 3

Chen in view of Kazakia teaches the method of claim 1 (see above) and Chen further teaches the step of acquiring with a tracking system the positions of the plurality of index points includes touching at least one of said index points with a trackable probe (pg. 12 line 12 – pg. 13 line 5).

In reference to Claim 4

Chen in view of Kazakia teaches the method of claim 4 (see above) and Chen further teaches said index points comprise at least three index points, three of said points defining a plane (see col. 12 lines 11-22).

In reference to Claim 5

Chen in view of Kazakia teaches the method of claim 3 (see above) and Chen teaches the index points define a coordinate system with known rotational relationship to said APP (i.e. that the index points lie on and define the APP).

17. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of Kazakia as applied to claim 1 above, and further in view of WO 01/21084 to Hodgson et al. ("Hodgson").

In reference to Claim 6

Chen in view of Kazakia teaches the method of claim 1 (see above), and Kazakia teaches the step of aligning comprises adjusting an adjustable portion of said frame in relation to said patient (see col. 5 lines 12-20), but neither appear to explicitly disclose that this occurs with said adjustable portion of said positioning frame detached from an operating table.

Hodgson teaches a method for contacting various points on the pelvis in which the contact blocks are adjusted with the patient in the standing position (see pg. 18 line 20 – col. 19 line 25). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Chen in view of Kazakia by detaching the frame from the operating table in order to adjust the ASIS and pubic

contact blocks as this simple substitution would predictably result in the user placing the contact blocks on the desired anatomical landmarks as taught by Hodgson and required by Kazakia.

In reference to Claim 7

Chen in view of Kazakia and Hodgson teaches the method of claim 6 (see above) and Hodgson further teaches the adjusting of said frame with the patient in either an upright or a supine position (see Fig. 1a and 1b and pg. 18 line 20 - pg. 18 line 25).

In reference to Claim 8

Chen in view of Kazakia and Hodgson teaches the method of claim 7 (see above). Kazakia further teaches relocating the patient onto an operating table; arranging said patient in the lateral decubitus position (see Fig. 2); and clamping said patient securely between said adjustable portion (100) of said frame on one side, and an opposing backrest (200) on the other to hold said patient's pelvis in fixed position. While the prior art does not explicitly teach that the relocating happens after adjusting the frame, the proposed combination would suggest this timing to one of ordinary skill in the art, as Hodgson teaches adjusting while the patient is standing and Kazakia teaches that the patient is placed on an operating table in the lateral decubitus position after adjustment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JP/ 3/8/10

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736

